REMARKS

It is respectfully submitted that the present response presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the following remarks is requested.

I. Continuation Examination and Response to Prior Argumentation

Applicants acknowledge with appreciation that the Examiner has entered the previously filed request for continued examination and considered the submission provided therewith.

Applicants further acknowledge with appreciation that the Examiner has withdrawn the prior rejections. The Examiner states, however, that upon further consideration, new grounds of rejection are made under 35 U.S.C. 103(a). Applicants address these new rejections in detail below.

II. The Rejection of Claims 1, 3, 5-7, 11, 14 and 17-21 under 35 U.S.C. 103(a)

Claims 1, 3, 5-7, 11, 14 and 17-21 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Winterbottom, CH 356 659, which reference is not in English, and over Winterbottom US 2,930,702 ("Winterbottom"). Applicants respond to both rejections with reference to the English-language US patent.

The Examiner states that Winterbottom discloses a method for producing a food product comprising contacting meat with lactobionic acid, whereby slaughtered poultry is submerged into the antibiotic solution, for a time of 30 minutes to 4 hours (marinate), allowed to freeze, packed and distributed to the market place, and then cooked. The Examiner states that although Winterbottom "discloses that the flesh of the poultry absorbs sufficient antibiotic matter to guarantee adequate protection" but acknowledges that Winterbottom does not expressly disclose that the amount is "sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid. Office Action, page 3 (citations omitted). The Examiner concludes however that "given that the poultry is soaked for at least 30 minutes in 3-30% lactobionic acid, and the references [sic] disclosure of a sufficient amount is absorbed; it is clear, absent any clear and convincing evidence to the contrary, that said sufficient amount would include 0.1-20% and which would be sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid." Office Action, page 3 (citations omitted).

The Examiner also contends that the product of claims 1 and 19-21 depends on the infusing process and that it would have been within the ambit of one of ordinary skill to proceed with the infusion process until the meat contains the desired weight percentage of each component. The Examiner contends that the variables to be modified are within the realm of routine experimentation.

This rejection is respectfully traversed.

As an initial matter, Applicants wish to reiterate their disagreement with the Examiner's position that Winterbottom teaches "that the poultry is soaked for at least 30 minutes in 3-30% lactobionic acid". Although their position was outlined at length in the prior response, Applicants reiterate it herein because the Examiner continues to maintain what Applicants believe to be an erroneous interpretation of the technical disclosure of Winterbottom.

The Compositions of Winterbottom: Winterbottom does not teach that poultry is soaked for at least 30 minutes in 3-30% lactobionic acid. At best, Winterbottom teaches that a diluted composition, not exceeding 90 ppm or 0.009% of lactobionic acid, is used to prepare a poultry dip solution.

Winterbottom discloses lactobionic acid as one of several non-toxic and water-soluble acids useful to be added to an antibiotic, such that no scumming, cloudiness, or precipitation of the antibiotic solution results.

The composition according to Winterbottom is diluted before contacting with poultry.

First, a ***dry composition*** is made:

> In terms of percent by weight, the composition of this invention should be one containing about 3 to 30% of the antibiotic, about 3 to 30% of the acid, about 1% of the surface active agent and the residue being made up of the diluent. The preferred composition is one containing about 10% chlortetracycline, 10% citric acid, 1% Tween 80 (polyoxyethylene sorbitan mono-oleate), and 79% sodium chloride (all percentages being by weight).

Winterbottom, col. 3, lines 32-36. Applicants assume for the sake of argument that the "3 to 30% of the acid" of the ***dry composition*** would include 3 to 30% of lactobionic acid (although Applicants do not concede that Winterbottom teaches the existence of or concentration of lactobionic acid in such ***dry composition*** is taught with particularity).

Second, the dry composition is diluted with water to produce a ***stock solution***:

> In commercial operation the dry composition described above is diluted with water to produce a stock solution containing above 1000 p.p.m. of the antibiotic. This concentration of the antibiotic in the stock can run as high as 10,000 p.p.m., or it might run much lower, for example, 500 p.p.m. However, the concentration 1000 p.p.m. is preferred, because if one goes below 1000 p.p.m., then the volume of liquid becomes excessively large and difficult to handle. If one goes to the other extreme, that of the 10,000 p.p.m., the antibiotic will be difficultly soluble in the water.

Winterbottom, col. 3, lines 41-51. Applicants assume for the sake of argument that the ***stock solution*** contains the disclosed extreme high 10,000 p.p.m. of antibiotic. Applicants further assume for the sake of argument that a ***stock solution*** could contain up to 30,000 p.p.m of lactobionic acid, because the proportions of the antibiotic will vary from 1 to 3 parts by weight of the acid to 1 part by weight of the antibiotic. Winterbottom, col. 3, lines 3-5. Again, however, Applicants do not concede that the existence of or concentration of lactobionic acid in such ***stock solution*** is taught with particularity.

Moreover, a ***stock solution*** is a concentrated solution used in commercial operation which is easier to handle as compared to (in this case) the dry composition disclosed in column 3, lines 32-40 of Winterbottom. When preparing the solution in which the poultry is to be dipped, it is easier (and more reproducible or standardized) to dilute the stock solution (having a known standardized concentration) than to start each time from scratch by weighing out and dissolving a specified amount of dry composition. The concentration of such stock solution should be as high as possible making it easy to handle and not taking up more space than is necessary. But if the limit of solubility of the antibiotic is approached, as explained in the paragraph bridging columns 1-2 of Winterbottom, a scum forms during the dissolving operation and cloudiness and precipitation take place on standing. Addition of acid is said to prevent this and the handling loss of the antibiotic is minimized. Based on the teachings of Winterbottom, the skilled person would never consider dipping the poultry into the stock solution, as the Examiner implies. It is only the next paragraph of Winterbottom (col. 3, lines 52-60) that discloses dilution of the stock solution into a "solution in which the poultry will ultimately be dipped".

Thus, the stock solution of Winterbottom is further diluted to provide a ***poultry dip solution***:

The recommended concentration of the antibiotic in the solution in which the poultry will ultimately be dipped may run anywhere from 3 p.p.m. to about 30 p.p.m. The preferred concentration of the antibiotic is that of about 10 p.p.m. Thus the procedure in preparing the solution in which the poultry is to be dipped is merely one of running a sufficient quantity of the stock solution into water to form a solution containing approximately 10 p.p.m. of the antibiotic.

By following this procedure one will produce a poultry dip solution containing in water about 10 p.p.m. of the antibiotic, about 10 p.p.m. of citric acid, about 1 p.p.m. of the non-toxic surface active agent, and about 79 p.p.m. of the inert non-toxic water-soluble diluent. This is the preferred composition of the dipping solution. The various amounts of the various constituents can however, be varied. The amount of the antibiotic should not exceed about 30 p.p.m., since amounts greater than this are not always removed by cooking. At the other extreme, amounts lower than 3 p.p.m. have been found not to be consistently effective in preserving poultry. The cost of the antibiotic and the other constituents is of course a major factor also in determining what quantities should be used in the dipping solution. Therefore, about 3 to 90 p.p.m. of citric acid, about 0.3 to 3 p.p.m. of the surface active agent, and about 60 to 240 p.p.m. of the inert water-soluble diluent are recommended.

Winterbottom, col. 3, line 61 to col. 4, line 3. Winterbottom expressly states that "the amount of the antibiotic [in the poultry dip solution] should not exceed about 30 p.p.m., since amounts greater than this are not always removed by cooking." Winterbottom, col. 3, lines 68-70. Again, Applicants assume for the sake of argument that a ***poultry dip solution*** contains the disclosed extreme high of 30 p.p.m. of antibiotic. Applicants further assume for the sake of argument that a ***poultry dip solution*** could contain up to 90 p.p.m of lactobionic acid, because the proportions of the antibiotic will vary from 1 to 3 parts by weight of the acid to 1 part by weight of the antibiotic. Winterbottom, col. 3, lines 3-5. Again, however, Applicants do not concede that the existence of or concentration of lactobionic acid in such ***poultry dip solution*** is taught with particularity.

Poultry of Winterbottom is then dipped in said ***poultry dip solution***.

> In carrying out the dipping procedure, freshly killed poultry, after being cleaned in the customary manner, is immersed in an ice water bath containing the above-described dipping solution. After the flesh has been chilled it is removed from the antibiotic bath and packaged by conventional methods, after which it can be distributed to the retail market.
>
> The poultry should remain in the dipping solution at least ½ hour. In this period, enough of the antibiotic is absorbed in the chicken flesh for adequate protection. A longer period of time, up to several hours is more desirable, since more of the antibiotic will be absorbed; two hours is preferred. The poultry should not be washed after the dipping process because it is the antibiotic on the surface which retards the bacterial growth. Individual packaging of poultry at the processing plant now made possible by the longer shelf life from the use of this antibiotic dipping process is a further safe guard against surface removal of the antibiotic and against bacterial contamination of the poultry during subsequent handling enroute to the consumer.

Winterbottom, col. 4, lines 4-24.

Thus, at best, according to Winterbottom, poultry is contacted with a hypothetical poultry dip solution containing a hypothetical 90 p.p.m. of lactobionic acid.

At best, Winterbottom teaches that a diluted composition, not exceeding 90 ppm or 0.009% of lactobionic acid, is used to prepare a poultry dip solution, in which poultry is theoretically soaked. It is simply not seen how the exposure of such a low percentage of lactobionic acid, which is ***far below*** the lower limit of the range of the claims, could result in the exposed poultry taking up so much lactobionic acid as to result in a food product comprising 0.1 and 20% (weight/weight) lactobionic acid.

Respectfully, Applicants disagree with the Examiner's assertion that Winterbottom teaches that "*poultry is soaked for at least 30 minutes in a solution containing 3-30% lactobionic acid.*" Applicants submit that there is simply no factual basis for the Examiner's position regarding the technical teachings of Winterbottom. For at least these reasons, Applicants respectfully submit that Winterbottom does not disclose a lactobionic acid solution, which upon contact with meat would expressly or inherently produce a food product comprising between 0.1 and 20 % (weight/weight) lactobionic acid, as required by the pending claims.

The Function of Lactobionic Acid: The Purpose of Added Lactobionic Acid in Winterbottom Teaches Away from the Present Claims

As is clear from the above discussion, Winterbottom is directed to processes for preserving dressed poultry. Winterbottom, Title. An improvement in the processing of fresh poultry is desirable in order to prolong its short shelf life. Column 1, lines 25-41. Winterbottom addresses the

problem whereby tetracycline antibiotics and their metallic acid salts used for preservation of freshly killed chicken, are observed to form an undesirable scum in the dissolving operation and cloudiness and precipitation on standing. Column 1, lines 55-62. While the reason or reasons for this scumming, cloudiness and precipitation are not fully understood, Winterbottom has identified that adding a solid, non-toxic water-soluble acid to the antibiotic results in no scumming, cloudiness or precipitation, even at antibiotic levels up to 10,000 ppm. Column 1, line 64 to column 2, line 20. Exemplary acids include lactobionic acid. Column 2, line 65 to col. 3, line 2. According to Winterbottom, it is highly unexpected that the acid should prevent this undesirable loss of the antibiotic in solution. Column 2, lines 41-43.

Thus, according to Winterbottom, the function of added lactobionic acid is to prevent scumming, cloudiness or precipitation of the desired tetracycline antibiotic solutions useful in preserving freshly killed chicken. Winterbottom provides absolutely no teaching or motivation to directly apply lactobionic acid alone to meat; at best, Winterbottom teaches the use of lactobionic acid as a mere adjunct for stabilizing the antibiotic solution useful in preserving meat. In fact, the function of lactobionic in Winterbottom as a mere adjunct for stabilizing the antibiotic solution teaches away from the present invention.

In contrast, the present invention as embodied in claim 1, is directed to a method for producing a food product comprising: a) contacting meat with lactobionic acid in an amount sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid; and b) producing a food product from the meat contacted with lactobionic acid, wherein the food product comprises between 0.1 and 20 % (weight/weight) lactobionic acid.

As set forth in the specification as filed, the present inventors have found that when lactobionic acid is included in a meat based product the water loss upon freezing and subsequent thawing and/or upon cooking is reduced compared to a meat based product not including lactobionic acid. Specification page 1, lines 23-25. Moreover, the amount of lactobionic acid in the final meat based food product is an amount sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product compared to the water loss of a similar food product prepared without lactobionic acid. The water loss upon freezing and subsequent thawing of the meat based food product prepared with lactobionic acid may, e.g., be reduced by 2% or more, such as by 5% or more, by 10% or more, or by 15% or more, compared to the water loss of a similar food product prepared without lactobionic acid. Specification page 2, lines 18-30.

Thus, in addition to providing lactobionic acid in an ***amount*** which is distinguishable from the disclosure of Winterbottom, as was discussed above, the present inventors have discovered an

entirely new ***functionality*** to the application of lactobionic acid for meat based food products.

Winterbottom does not teach or suggest that contacting meat with lactobionic acid in an amount sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid. For at least these reasons, Applicants respectfully submit that the amended claims are not rendered obvious by Winterbottom.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claims 2, 4, 8-10 and 12-13 under 35 U.S.C. 103(a)

Claims 2, 8-10 and 12 remain rejected under 35 U.S.C. 103(a) as unpatentable over Winterbottom in view of Roselle et al., USPN 6,773,737 ("Roselle"). Claim 4 stands rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Winterbottom in view of Halden et al. EP 0 354 262 ("Halden"). Claim 13 stands rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Winterbottom in view of Hayashabira GB Patent No. 1 325 727 ("Hayashabira").

Winterbottom is cited as above.

Roselle is cited as disclosing a method for treating food products with a solution containing calcium lactobionate, where the food product is in the form of beef, pork, chicken and shellfish.

Halden is cited as teaching marinating meat by tumbling.

Hayashabira is cited as teaching lactobionic acid from lactose by enzymatic oxidation.

Applicants respectfully traverse the rejection.

As discussed above, Winterbottom does not disclose or suggest the pending claims. For at least the reasons set forth above regarding Winterbottom alone, neither does Winterbottom in combination with Roselle, Halden and/or Hayashabira teach or suggest the pending claims.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

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